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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,632	12/08/2003	Chau-Ting Yeh	14176-003001	9429

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EXAMINER

MONTANARI, DAVID A

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,632	YEH, CHAU-TING	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 13 and 15-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12, and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants arguments and amendments filed 12/27/05 have been entered.
2. Claim 12 is amended.
3. The declaration by Chau-Ting Yeh has been considered.
4. Rejection of claims 1-6 and 14 under 35 USC 101, double patenting is withdrawn.
5. Claims 1-6, 12, and 14 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 12 and 14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence disclosed in SEQ ID NO: 1, wherein the presence of the said nucleic acid in a subject predisposes the subject to an abnormal liver condition comprising either non-A-E hepatitis, hepatitis B, hepatitis C or a combination thereof or colon cancer and wherein said nucleic acid is present in an isolated cell, does not reasonably provide an isolated nucleic acid comprising a nucleotide sequence having at least 70% identity to SEQ ID NO: 1, wherein the presence of the said nucleic acid in a subject predisposes the subject to any abnormal liver condition or adenocarcinoma and a cell comprising an isolated nucleic acid comprising a nucleotide sequence of at least 70% identity to SEQ ID NO: 1 wherein said cell express the nucleic acid. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record in the office action mailed 08/23/2005.

Response to Arguments

Applicants argue in amendment filed 12/27/2005 that claim 12 was originally not considered in the previous office action. The examiner apologizes for this oversight, and claim 12 is now considered and examined along with claims 1-6 and 14. However, claim 12 when examined for its full breadth would be encompassed in the enablement rejection in the previously mailed office action for the same reasons that claims 1-6, and 14 stand rejected. Applicants have provided a declaration by the inventor Chau-Ting Yeh to answer the examiners issues and questions regarding the enablement rejection. The examiner has fully considered Mr. Yeh's declaration, however this is not fully persuasive. At issue is the predisposition to an abnormal liver condition that the applicant claims occurs when an isolated nucleic acid comprising a nucleotide sequence at least 70% identical to SEQ ID NO: 1 is present in a subject. On page 4 of Mr. Yeh's declaration he states in line 7 that NV-F encodes a protein that correlates with hepatitis. However, this correlation does not infer that NV-F predisposes a subject to an abnormal liver condition, and may in fact occur because of an abnormal liver condition. That the two occur at the same time does not mean that NV-F results in an abnormal liver condition. In view of Mr. Yeh's declaration, the examiner accepts that full-length SEQ ID NO: 1 does encode a protein, and that protein can be expressed in cells. However, the examiner maintains that only the full-length SEQ ID NO: 1, as discussed previously in the enablement rejection, has these

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properties, and that isolated nucleic acids comprising a nucleotide sequence at least 70%, 80%, 90%, and 95% are still rejected for lack of enablement discussed in the previous office action.

With regard to claim 12 the issues again are the same as discussed above. There is no teaching in the instant specification of an isolated nucleic acid characterized in that it hybridizes under stringent conditions to SEQ ID NO: 1, or a complementary sequence thereof wherein said presence of the nucleic acid predisposes a subject to an abnormal liver condition. Since only the full-length SEQ ID NO: 1 is known to code for a protein, and it is still unclear if indeed this protein does predispose a subject to an abnormal liver condition, this issue remains for claim 12 as well. Thus for reasons of record in the office action mailed 08/23/2005 and above the rejection is maintained.

Claims 1-6, and 14 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Arguments

Applicants argue in amendment filed 12/27/2005 that sufficient guidance is provided by the specification to meet the written description requirement of claims 1-6, 12, and 14.

Applicants argue that it is well known in the art that nucleotide sequences of at least 70% identical to a probe sequence, e.g., SEQ ID NO: 1, would hybridize to the probe or its complement under highly stringent conditions. Applicants continue to argue that procedures for

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making variants of SEQ ID NO: 1 are conventional in the art and an assay is described which will identify other variants having activity. This is not persuasive.

Though a scientific procedure is routine in the art, does not mean that the rejected claims possess adequate written description. As discussed in the previous office action, there is a lack of teaching by the specification that would identify specific characteristics that would show that applicant was in possession of the rejected nucleic acid sequence at the time of filing. The argument that something is routine does not support that applicant was in possession of isolated nucleic acids comprising a nucleotide sequence at least 70%, 80%, 90%, and 95% of SEQ ID NO: 1 at the time of filing, and is not persuasive. Thus for reasons of record in the office action mailed 08/23/2005 and above the rejection is maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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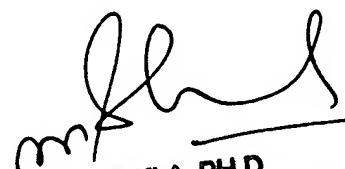
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Montanari, PhD


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER